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(d) Send notice to the applicant that additional test data must be submitted and specify what tests are necessary and how the tests shall be interpreted (in such cases, the 120-day period shall commence upon receipt of the additional test data).

(e) Send notice to the applicant that the application has been found to be substantially deficient or incomplete and cannot be processed until additional information is submitted to complete the application and specify the general areas of substantial deficiency.

(f) Send notice to the applicant that additional tests will be conducted by the Administrator, specifying the nature of and reasons for the additional tests and the estimated time required (in such cases, the 120-day period shall commence 1 calendar day after the additional tests have been completed).

[71 FR 61271, Oct. 17, 2006]

§ 53.6 Right to witness conduct of tests.

(a) Submission of an application for a reference or equivalent method determination shall constitute consent for the Administrator or the Administrator's authorized representative, upon presentation of appropriate credentials, to witness or observe any tests required by this part in connection with the application or in connection with any modification or intended modification of the method by the applicant.

(b) The applicant shall have the right to witness or observe any test conducted by the Administrator in connection with the application or in connection with any modification or intended modification of the method by the applicant.

(c) Any tests by either party that are to be witnessed or observed by the other party shall be conducted at a time and place mutually agreeable to both parties.

§ 53.7 Testing of methods at the initiative of the Administrator.

(a) In the absence of an application for a reference or equivalent method determination, the Administrator may conduct the tests required by this part for such a determination, may compile

such other information as may be necessary in the judgment of the Administrator to make such a determination, and on the basis of the tests and information may determine that a method satisfies applicable requirements of this part.

(b) In the absence of an application requesting the Administrator to consider revising an appendix to part 50 of this chapter in accordance with § 53.16, the Administrator may conduct such tests and compile such information as may be necessary in the Administrator's judgment to make a determination under § 53.16(d) and on the basis of the tests and information make such a determination.

(c) If a method tested in accordance with this section is designated as a reference or equivalent method in accordance with § 53.8 or is specified or designated as a reference method in accordance with § 53.16, any person or entity who offers the method for sale as a reference or equivalent method thereafter shall assume the rights and obligations of an applicant for purposes of this part, with the exception of those pertaining to submission and processing of applications.

§ 53.8 Designation of reference and equivalent methods.

(a) A candidate method determined by the Administrator to satisfy the applicable requirements of this part shall be designated as a FRM or FEM (as applicable) by and upon publication of a notice of the designation in the FEDERAL REGISTER.

(b) Upon designation, a notice indicating that the method has been designated as a FRM or FEM shall be sent to the applicant.

(c) The Administrator will maintain a current list of methods designated as FRM or FEM in accordance with this part and will send a copy of the list to any person or group upon request. A copy of the list will be available via the Internet and may be available from other sources.

[71 FR 61276, Oct. 17, 2006, as amended at 75 FR 35597, June 22, 2010]

§ 53.9 Conditions of designation.

Designation of a candidate method as a FRM or FEM shall be conditioned to

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the applicant's compliance with the following requirements. Failure to comply with any of the requirements shall constitute a ground for cancellation of the designation in accordance with § 53.11.

(a) Any method offered for sale as a FRM or FEM shall be accompanied by a copy of the manual referred to in § 53.4(b)(3) when delivered to any ultimate purchaser, and an electronic copy of the manual suitable for incorporating into user-specific standard operating procedure documents shall be readily available to any users.

(b) Any method offered for sale as a FRM or FEM shall generate no unreasonable hazard to operators or to the environment during normal use or when malfunctioning.

(c) Any analyzer, PM₁₀ sampler, PM_{2.5} sampler, or PM_{10-2.5} sampler offered for sale as part of an FRM or FEM shall function within the limits of the performance specifications referred to in § 53.20(a), § 53.30(a), § 53.35, § 53.50, or § 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in § 53.4(b)(3).

(d) Any analyzer, PM₁₀ sampler, PM_{2.5} sampler, or PM_{10-2.5} sampler offered for sale as a FRM or FEM shall bear a prominent, permanently affixed label or sticker indicating that the analyzer or sampler has been designated by EPA as a FRM or FEM (as applicable) in accordance with this part and displaying any designated method identification number that may be assigned by EPA.

(e) If an analyzer is offered for sale as a FRM or FEM and has one or more selectable ranges, the label or sticker required by paragraph (d) of this section shall be placed in close proximity to the range selector and shall indicate clearly which range or ranges have been designated as parts of the FRM or FEM.

(f) An applicant who offers analyzers, PM₁₀ samplers, PM_{2.5} samplers, or PM_{10-2.5} samplers for sale as FRM or FEMs shall maintain an accurate and current list of the names and mailing addresses of all ultimate purchasers of such analyzers or samplers. For a period of 7 years after publication of the

FRM or FEM designation applicable to such an analyzer or sampler, the applicant shall notify all ultimate purchasers of the analyzer or sampler within 30 days if the designation has been canceled in accordance with § 53.11 or § 53.16 or if adjustment of the analyzer or sampler is necessary under § 53.11(b).

(g) If an applicant modifies an analyzer, PM₁₀ sampler, PM_{2.5} sampler, or PM_{10-2.5} sampler that has been designated as a FRM or FEM, the applicant shall not sell the modified analyzer or sampler as a reference or equivalent method nor attach a label or sticker to the modified analyzer or sampler under paragraph (d) or (e) of this section until the applicant has received notice under § 53.14(c) that the existing designation or a new designation will apply to the modified analyzer or sampler or has applied for and received notice under § 53.8(b) of a new FRM or FEM determination for the modified analyzer or sampler.

(h) An applicant who has offered PM_{2.5} or PM_{10-2.5} samplers or analyzers for sale as part of a FRM or FEM may continue to do so only so long as the facility in which the samplers or analyzers are manufactured continues to be an ISO 9001-registered facility, as set forth in subpart E of this part. In the event that the ISO 9001 registration for the facility is withdrawn, suspended, or otherwise becomes inapplicable, either permanently or for some specified time interval, such that the facility is no longer an ISO 9001-registered facility, the applicant shall notify EPA within 30 days of the date the facility becomes other than an ISO 9001-registered facility, and upon such notification, EPA shall issue a preliminary finding and notification of possible cancellation of the FRM or FEM designation under § 53.11.

(i) An applicant who has offered PM_{2.5} or PM_{10-2.5} samplers or analyzers for sale as part of a FRM or FEM may continue to do so only so long as updates of the Product Manufacturing Checklist set forth in subpart E of this part are submitted annually. In the event that an annual Checklist update is not received by EPA within 12 months of the date of the last such submitted Checklist or Checklist update,

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EPA shall notify the applicant within 30 days that the Checklist update has not been received and shall, within 30 days from the issuance of such notification, issue a preliminary finding and notification of possible cancellation of the reference or equivalent method designation under § 53.11.

[71 FR 61276, Oct. 17, 2006, as amended at 78 FR 3281, Jan. 15, 2013]

§ 53.10 Appeal from rejection of application.

Any applicant whose application for a reference or equivalent method determination has been rejected may appeal the Administrator's decision by taking one or more of the following actions:

(a) The applicant may submit new or additional information in support of the application.

(b) The applicant may request that the Administrator reconsider the data and information already submitted.

(c) The applicant may request that any test conducted by the Administrator that was a material factor in the decision to reject the application be repeated.

§ 53.11 Cancellation of reference or equivalent method designation.

(a) *Preliminary finding.* If the Administrator makes a preliminary finding on the basis of any available information that a representative sample of a method designated as a reference or equivalent method and offered for sale as such does not fully satisfy the requirements of this part or that there is any violation of the requirements set forth in § 53.9, the Administrator may initiate proceedings to cancel the designation in accordance with the following procedures.

(b) *Notification and opportunity to demonstrate or achieve compliance.* (1) After making a preliminary finding in accordance with paragraph (a) of this section, the Administrator will send notice of the preliminary finding to the applicant, together with a statement of the facts and reasons on which the preliminary finding is based, and will publish notice of the preliminary finding in the FEDERAL REGISTER.

(2) The applicant will be afforded an opportunity to demonstrate or to achieve compliance with the require-

ments of this part within 60 days after publication of notice in accordance with paragraph (b)(1) of this section or within such further period as the Administrator may allow, by demonstrating to the satisfaction of the Administrator that the method in question satisfies the requirements of this part, by commencing a program to make any adjustments that are necessary to bring the method into compliance, or by taking such action as may be necessary to cure any violation of the requirements of § 53.9. If adjustments are necessary to bring the method into compliance, all such adjustments shall be made within a reasonable time as determined by the Administrator. If the applicant demonstrates or achieves compliance in accordance with this paragraph (b)(2), the Administrator will publish notice of such demonstration or achievement in the FEDERAL REGISTER.

(c) *Request for hearing.* Within 60 days after publication of a notice in accordance with paragraph (b)(1) of this section, the applicant or any interested person may request a hearing as provided in § 53.12.

(d) *Notice of cancellation.* If, at the end of the period referred to in paragraph (b)(2) of this section, the Administrator determines that the reference or equivalent method designation should be canceled, a notice of cancellation will be published in the FEDERAL REGISTER and the designation will be deleted from the list maintained under § 53.8(c). If a hearing has been requested and granted in accordance with § 53.12, action under this paragraph (d) will be taken only after completion of proceedings (including any administrative review) conducted in accordance with § 53.13 and only if the decision of the Administrator reached in such proceedings is that the designation in question should be canceled.

§ 53.12 Request for hearing on cancellation.

Within 60 days after publication of a notice in accordance with § 53.11(b)(1), the applicant or any interested person may request a hearing on the Administrator's action. If, after reviewing the request and supporting data, the Administrator finds that the request